DETAILED ACTION

Response to Amendment

The amendment and Request for Continued Examination (RCE) filed on 11/16/10 have been entered in the case. Claims 34-38 are pending for examination and claims 1-33 have been cancelled.

Applicant's amendments and arguments filed in 11/16/10 with respect to the rejection(s) of claim(s) 34-38 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as following:

Specification

The disclosure is objected to because of the following informalities:

[0057] Now with reference to Figs. 5 and 6, to further ensure that the proximal catheter end regions 112, 132 ~~134~~ remain secured in the subcutaneous area 16 of the body 14, the hub 150 is secured to the assembly 100 by placing the catheters 110, 130 into the bottom hub portion 162 such that the first transition portion 186 is disposed in the first proximal channel 158 and the second transition portion 188 is disposed in the second proximal channel 159, with a portion of the first and second catheters 110, 130 distal of the first and second transition portions 186, 188 ~~156, 157~~ being disposed within the distal channel 155. The top hub portion 160 is pivoted about the hinge

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 36, the limitation "the first and second catheters have transition section between the circular cross-sectional shapes of the first and second proximal and distal end regions and the semicircular cross-

shapes of the first and second intermediate sections" is unclear. The examiner cannot determine the position of the transition sections, i.e., are the transition sections located in between the first and second proximal and distal end regions? Or between the proximal end regions and the semicircular cross-sectional shapes of the first and second intermediate sections? Or between the proximal end regions of the catheters and the semicircular cross-section at intermediate sections thereof? From instant Figs. 1 and 8, it appears that perhaps applicant is referring to the transition sections 186, 188 being located in between the proximal end and distal end regions of the catheters, or alternatively that the transition sections 186, 188 are located in between the proximal end regions of the catheters and the semicircular cross-sectional shapes of the first and second intermediate sections. For purposes of examination, the examiner will assume this limitation means either a) the first and second catheters have transition sections between the circular cross-sectional shapes of the first and second proximal and distal end regions; or b) the transition sections 186, 188 are located in between the proximal end regions of the catheters and the semicircular cross-sectional shapes of the first and second intermediate sections.

Claims 37-38 are rejected due to their dependency on claim 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

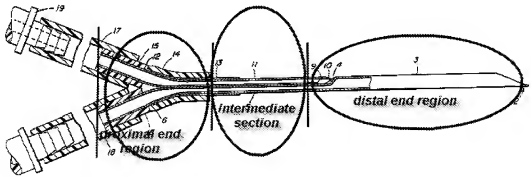
Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Consalvo (US 4,098,275) in view of either Cianci (US 4,149,539) or Raulerson (US 4,037,599).

Regarding claim 34, Consalvo discloses a multiple catheter assembly shown in Fig. 7 comprising:

a first catheter 1 having a first distal end region 1 and a first proximal end region (at portion of element 16, see Fig. markup below) joined by a first intermediate section 11;

a second catheter 7 having a second distal end region 9 and a second proximal end region (at portion of element 15, see Fig. markup below) joined by a second intermediate section 5;

first and second extension tube assemblies 17 and 18 having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters; and a hub member 14 located around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof. As to the limitation "after catheter implantation and subcutaneous tunneling and at a site selected by the practitioner along coextending lengths of the first end second proximal end regions spaced from the proximal ends thereof" this is a functional limitation which only requires the ability to so perform. In this case, Consalvo clearly shows in Fig. 7 implantation and subcutaneous tunneling of a catheter at a site selected by the practitioner along coextending length of the first and second proximal end regions spaced from the proximal ends thereof, such that portions of the proximal end regions (at portions of element 15, 16) of the first and second catheters 1 and 7 extend through a hub member 14 and proximally beyond the proximal end of the hub member through respective exits and spaced apart from each other, to be connected to respective ones of the first 17 and second 18 extension tube assemblies, with other portions of the proximal end regions of the first and second catheters extend distally from the hub member separately from but adjacent to each other, see Fig. 1.



It has been held that the recitation "adapted to/capable of to be releasably attachable by a practitioner..." performing a function is not a positive limitation but only requires the ability to so perform. In re Hutchison, 69 USPQ 138. In this case, as seen in Fig. 1 or 7 of Consalvo, the hub member 14 of Consalvo is attachable

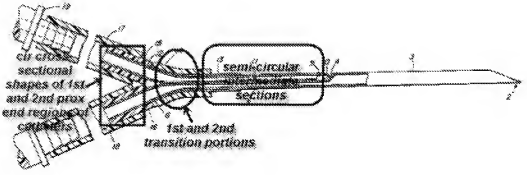
but is not releasable. However, claim 34 only requires that the hub member is adapted to be releasably attachable by a practitioner. Therefore, the hub member of Consalvo can be used or modified with another releasably attachable hub member of either Cianci or Raulerson.

Cianci discloses a catheter assembly comprising: a catheter 20; a hub member 18; wherein the catheter 20 is removably and attachable to the hub member 18 by a practitioner directly to and around the proximal regions of the catheter 20.

Raulerson discloses a catheter assembly comprising: a catheter 14, an initially separate hub member 12; wherein the hub member 12 comprises a hinge line folding of one hub portion relative to the hinge line into mating engagement with other hub portion will serve to open or close, see col. 3, lines 40-45, and Fig. 3. In other words, the hub member of Raulerson is adapted to be releasably attachable by a practitioner. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Consalvo with a hub assembly, as taught by either Cianci or Raulerson, for the benefit of easy attachability or detachability between the catheter device and the hub member.

Regarding claim 35, Consalvo discloses that the rear portion or coupling end 6 of the venous tube (or first catheter) 1 has a circular cross-sectional area, col. 4, lines 9-10 and see Fig. 2. As seen in Fig. 1, the rear portion 12 of arterial tube (or second catheter) 7 has identical cross-sectional area as that of the rear portion 6 the first catheter 1, the cross-sectional shapes of the first 6 and second 13 proximal end regions are circular, and the cross-sectional shapes of the first and second distal end portions of the first 17 and second 18 extension tube are circular, see Figs. 1 and 2.

Regarding claim 36, Consalvo discloses that the cross-sectional shapes of the first and second intermediate sections 5 and 11 of the first and second catheters 1 and 7 are semicircular (see Fig. 5 or col. 4, lines 2-5 and lines 31-33). According to Fig. 1, Consalvo shows that the transition sections are located in between the circular cross-sectional shapes of the first and second proximal regions of the catheters and semicircular cross-sectional shapes of the first and second intermediate sections 5 and 11, as shown in the marked up figure below.



Regarding claims 37-38, Consalvo discloses that the first and second intermediate sections 1 and 5 of the first and second catheters 1 and 7 are splittably joined to each other; wherein the first and second intermediate sections 11 and 5 of the first and second catheters 1 and 7 are splitably joined to each other by adhesive, col. 6, lines 54-56 and see Fig. 5.

Response to Arguments

Applicant's arguments with respect to claims 34-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Quynh-Nhu H. Vu/
Examiner, Art Unit 3763